HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF EPIDEMIOLOGY, ENVIRONMENTAL AND OCCUPATIONAL HEALTH

CONSUMER, ENVIRONMENTAL, AND OCCUPATIONAL HEALTH SERVICES

PUBLIC HEALTH AND FOOD PROTECTION PROGRAM

Adopted Readoption with Amendments: N.J.A.C. 8:27

Adopted Repeals: N.J.A.C. 8:27-4.3 and 4.7

Adopted Repeal and New Rules: N.J.A.C. 8:27-8, 9.1, 11.1, and 11.5

Adopted New Rules: N.J.A.C. 8:27-4.1, 4.4, 4.8, 4.9, and 8:27 Appendix Body Art and Ear-Piercing Facility Standards

Proposed: February 7, 2022 at 54 N.J.R. 229(a)

Adopted: _____, 2022, by _____

Judith M. Persichilli, RN, BSN, MA

Commissioner, Department of Health, in consultation with the Public Health Council.

Filed: , 2022, as R. 2022 d. , **with proposed N.J.A.C. 8:26-2.6(a)6, N.J.A.C. 8:27-4.9(a)1, N.J.A.C. 8:27-4.9(c), N.J.A.C. 8:27-8.1(d)1, N.J.A.C. 8:27-8.1(d)2, N.J.A.C. 8:27-8.1(e)1, N.J.A.C. 8:27-8.1(e)2, and N.J.A.C. 8:27-11.2(a) not adopted**

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Authority: N.J.S.A. 24:1-1 et seq., particularly 24:2-1, 24:5-18, and 24:17-1 et seq., and 26:1A-7(n), (o), and (p); and Reorganization Plan No. 003-2005 (Governor Codey, June 27, 2005).

Effective Date:

Expiration Date:

Summary of Public Comments and Agency Responses:

The Department of Health (Department) received timely comments from the following commenters during the 60-day public comment period, which ended on April 8, 2022.

1. Luis Garcia, VP Association of Professional Piercers and 12 oz. Studios;

2. Troy Timpel, Villainarts.com and host of the annual Wildwood Beach Bash;

3. Amber DeGruttola, Looking Glass Tattoos;

4. Dawn Kozlowski;

5. Michael Siderio, Rebel Image Tattoo;

6. Caroline Evans, Secretary, Alliance of Professional Tattooists, Inc.;

7. John Protonentis, Ocean County Health Department;

8. Jillian Lamanna, Alliance of Professional Tattooists, Inc.;

9. Jennifer Carmean, Alliance of Professional Tattoo Artists state representative and Monarch Tattoo;

10. Suzanne Fajgier, Burlington County Health Department;

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11. Richard Cahill, Anchors Aweigh Tattoo;

12. Joseph Dillon, Ink Therapy Tattoo;

13. Rose Marie Beauchemin-Verzella, American Academy of Micropigmentation;

14. Brendan Lynch;

15. Derrick Webb, New Jersey Association of City and County Health Officials (NJACCHO) – Environmental and Consumer Health Workgroup.

1. COMMENT: One commenter stated, “Thank you for these revisions. They were a long time coming and we are grateful to the Legal Department for their hard work.” (13)

RESPONSE: The Department thanks the commenter for the comment in support of this rulemaking.

2. COMMENT: Two commenters objected to proposed N.J.A.C. 8:27-1.2(b), stating that health care providers should not be exempt from the proposed rule. (5,13)

RESPONSE: The Department disagrees with the comments. Physicians and physician assistants are authorized to perform tattooing pursuant to N.J.S.A. 45:9-1 et seq. Accordingly, the Department adopts N.J.A.C. 8:27-1.2(b) as proposed.

3. COMMENT: One commenter stated with respect to the proposed definition of After-care instruction at N.J.A.C. 8:27-1.3 that the commenter agrees that after-care is a must and that educating the client is the best course of action. The comment goes on to state that the ultimate responsibility for healing rests with the client. (5)

RESPONSE: The Department thanks the commenter for his support of the definition of “After-care” and acknowledges that the client should follow the after-care instructions to

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promote healing. Accordingly, the Department adopts the definition of “After-care” at N.J.A.C. 8:27-1.3 as proposed.

4. COMMENT: One comment stated that the Department should change the term “permanent cosmetics” at N.J.A.C. 8:27-1.3 to the term “cosmetic tattooing” because the term expresses more clearly that it is a tattoo procedure. (10)

RESPONSE: The Department disagrees with the comment that permanent cosmetics is a tattoo procedure. Permanent cosmetics is a distinct form of body art that requires different and specialized training, utilizes different instruments, utilizes different motions and techniques, requires skin tone matching via pigmentation, and inserts pigments at a shallower depth in the skin than tattooing. Given these significant differences, the Department has determined that the public would be better served by using terms that recognize the distinctions between permanent cosmetics and tattooing. Accordingly, the Department adopts the definition of “permanent cosmetics” in N.J.A.C. 8:27-1.3 as proposed.

5. COMMENT: One commenter stated that many definitions should not have been removed from N.J.A.C. 8:27-1.3, including “Apprentice,” “Biological Indicator,” “Body Art Establishment,” “Body Piercing,” “Chemical Integrator,” “Contaminated Waste,” “Sterilization,” and “Tattooing.” (7)

RESPONSE: The comment is outside the scope of the proposed rulemaking. The defined terms named in the comment are still a part of N.J.A.C. 8:27-1.3. Pursuant to the OAL Rules for Agency Rulemaking, definitions proposed for deletion or amendment at N.J.A.C. 8:27-1.3 were published in the rule proposal at 54 N.J.R. 229(a). Definitions

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that were proposed for readoption without change were not required to be published in the rule proposal and are hereby readopted.

6. COMMENT: One commenter asked, “On page 41 of the revision there is a new definition for “Standard Precautions” referencing a 2007 Guideline. Do we have that guideline or can it be spelled out in the revision?” (7)

RESPONSE: The Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., permits State agencies to incorporate guidelines by reference because it is not practical to print them out in a rule due to length and high volume of content. As stated in the rule proposal, the proposed definition of “Standard Precautions” in N.J.A.C. 8:27-1.3 may be found at the following weblink: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html. Accordingly, the Department adopts the rule as proposed.

7. COMMENT: One commenter proposed to amend the requirements of the definition of “Trainer or instructor of permanent cosmetics” in N.J.A.C. 8:27-1.3 to state that “…they must be a certified instructor trainer by either AAM, SPCP or Soft-Tap and a minimum of 3 years’ experience …” (13)

RESPONSE: The Department disagrees with the comment. The proposed definition already provides that certified trainers or instructors of permanent cosmetics are credentialed by the American Academy of Micropigmentation, Society of Permanent Cosmetic Professionals, or SofTap. The Department believes that the aforementioned organizations’ standards for certified trainers and instructors are adequate and appropriate in demonstrating competency to train persons in permanent cosmetics

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procedures. The comment suggesting that a minimum of 3 years' experience should be a requirement for certification should be determined by the AAM, SPCP, and SofTap, Inc. Accordingly, the Department adopts the definition of "Trainer or instructor of permanent cosmetics" in N.J.A.C. 8:27-1.3 as proposed.

8. COMMENT: One commenter stated that proposed N.J.A.C. 8:27-2.6(a)6 is confusing with regard to where areola restoration, camouflage, and microblading procedures can be performed. (13)

RESPONSE: The Department agrees with the comment. As proposed, N.J.A.C. 8:27-2.6(a)6 may be interpreted to operate as a ban on the performance of areola restoration, camouflage, and microblading procedures in body art establishments, even if these establishments have a separate room for the performance of permanent cosmetics, as required by N.J.A.C. 8:27-3.1(d)1. The Department intended the rule to be interpreted as allowing areola restoration, camouflage, and microblading procedures to be performed in body art establishments, so long as the separate room requirement of N.J.A.C. 8:27-3.1(d) is met. Accordingly, the Department does not adopt N.J.A.C. 8:27-2.6(a)6 as proposed. N.J.A.C. 8:27-2.6(a)7 and 2.6(a)8 are hereby recodified as N.J.A.C. 8:27-2.6(a)6 and 2.6(a)7.

9. COMMENT: One commenter stated that "there needs to be better provision for enforcement and penalty for persons found performing body art work in an unlicensed location, such as a residence. There needs to be clear enforcement and penalty for a body art establishment that is operating without an operator on the premises where a practitioner is performing body art work." (7)

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RESPONSE: The Department disagrees with the comment. N.J.A.C. 8:27-2.6 and N.J.A.C. 8:27-11 adequately addresses enforcement and penalties within the ambit of the law, are clearly prescribed, protective of public health, and provide adequate enforcement tools for health authorities, particularly for addressing unlicensed and recalcitrant establishments. Accordingly, the Department adopts the enforcement provisions of N.J.A.C. 8:27-2.6 and N.J.A.C. 8:27-11 as proposed.

10. COMMENT: One commenter stated that the requirement in N.J.A.C. 8:27-2.7 for practitioner malpractice insurance is unnecessary. (5)

RESPONSE: The comment is outside the scope of the proposed rulemaking because the Department did not propose to repeal, amend, or establish a new rule at N.J.A.C. 8:27-2.7. Nevertheless, the Department supports the necessity of each practitioner to be covered by malpractice insurance to protect both the practitioner and the client from claims for injury or illness arising from improperly performed body art procedures. Accordingly, the Department readopts N.J.A.C. 8:27-2.7 without change.

11. COMMENT: One commenter states that the Department should accept “event insurance” in lieu of individual professional malpractice insurance policies for tattoo events in satisfaction of the insurance requirements at N.J.A.C. 8:27-2.7. (2)

RESPONSE: The comment is outside of the scope of the proposed rulemaking. Nevertheless, the Department accepts event insurance as meeting the requirements of N.J.A.C. 8:27-2.7 provided that the event insurance policy, with or without riders or other addenda, clearly states that each practitioner is covered for malpractice during the

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course of the event. Accordingly, the Department readopts existing N.J.A.C. 8:27-2.7 without amendments.

12. COMMENT: One comment stated that with respect to N.J.A.C. 8:27-4.2(c), an exception should be made for bottled water so as to allow for the client to stay hydrated during tattooing to avoid becoming light-headed, which is possible for some individuals.

RESPONSE: The comment is outside the scope of this rulemaking, which did not propose changes to the text of N.J.A.C. 8:27-4.2. Regardless, the Department notes that there is nothing in the existing rules or this proposal that would prohibit a client from taking a break during a long tattoo procedure and hydrating outside of the work area in an area permitted by existing N.J.A.C. 8:27-4.2(c).

13. COMMENT: One commenter states that proposed N.J.A.C. 8:27-4.4, which would require that areola restoration or camouflage only be performed in accordance with a healthcare provider's written instructions, is too burdensome for most clients. The comment states that the rule should only require the client to obtain "medical clearance" from a healthcare provider prior to receiving areola restoration or camouflage. The comment states that healthcare providers, concerned with personal liability issues, generally do not want to provide detailed and meaningful instructions. The comment further states that the requirements for "Written instructions, guideline and treatment plan" will provide undue duress for the client and practitioner and will limit the ability of practitioners to perform this service and clients to receive this valuable and often life changing procedure. The commenter proposes that the Department change the wording of the rule to only require a "medical clearance" letter from a health care provider.

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(13)

RESPONSE: The Department disagrees with the comment. Areola restoration is a permanent cosmetics procedure that is performed after breast or areola removal surgery or after traumatic injury to the areola. These medical conditions warrant at least specific written instructions issued by the health care provider. The comment incorrectly states that the proposed rule requires the healthcare provider to provide written instructions, guidelines and a treatment plan. The proposed rule instead only requires specific written instructions. The rule does not prescribe what must be contained in the specific written instructions and leaves that decision up to the discretion of the healthcare provider. The Department will consider the commenter's suggestion to only require a medical clearance letter from a healthcare provider in discussions with stakeholders about future rulemakings. Accordingly, the Department adopts N.J.A.C. 8:27-4.4 as proposed.

14. COMMENT: One commenter objected to the reporting requirements for infections following body art procedures in proposed N.J.A.C. 8:27-4.6 on the ground that preventing infections is the client's responsibility. (5)

RESPONSE: The Department disagrees with the comment. Existing N.J.A.C. 8:27-4.5, now recodified as N.J.A.C. 8:27-4.6, contains reporting requirements for operators, so reporting is not a new requirement. The Department notes, however, that proposed N.J.A.C. 8:27-4.6(a)2, which would require operators to maintain a written record of adverse reactions with the client's application for a procedure is a new requirement. Complying with this requirement would require very little time and could prove valuable

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to local health authorities, which are responsible for noting all incidents of illness or injury occurring during or after a body art procedure. This reporting system will help determine whether there are any unusual patterns or outbreaks attributed to a particular practitioner, establishment, brand of pigment, etc. and enable health authorities to quickly intercede to prevent further illness or injury. For all of these reasons, the Department adopts N.J.A.C. 8:27-4.6 as proposed.

15. COMMENT: One comment stated that the proposed requirement at N.J.A.C. 8:27-4.7(e)3, which would require operators to require practitioners, apprentices, and workers who have an acute respiratory infection or suspected or confirmed communicable disease to not be present at the body art establishment and to not return to the body art establishment until the operator receives written documentation from a health care provider that the condition is not transmissible, which the operator shall retain on file, is overly burdensome because it would require permanent recordkeeping of the average cold. In addition, the comment states that it would be ridiculous to ask artists to pay $300.00 or more for a walk-in appointment that may take 3 weeks to arrange. (6)

RESPONSE: The Department disagrees with the comment. The Department's intent in proposing N.J.A.C. 8:27-4.7(e)3 is not to require written documentation in connection with a common cold. The intent of the proposed rule is to limit the spread of communicable diseases and acute respiratory infections. The rule would require operators to establish policies and procedures that ensure that practitioners, apprentices, and workers do not expose clients to the risk of serious illnesses. The

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requirement of obtaining a doctor's note for these exceptional circumstances is not overly burdensome given that urgent care centers offer same day walk in service throughout the State. Since the New Jersey Health Insurance Market Protection Act of 2018 requires most people to have health insurance, the cost is limited to a copay, generally between $40.00 and $75.00. The Department acknowledges that for individuals without health insurance, the cost generally ranges from $120.00 to $280.00 depending on location and services rendered. Since most people in the State have health insurance, and since the need to prevent the spread of communicable diseases and serious illnesses is compelling, the Department adopts N.J.A.C. 8:27-4.7(e)3 as proposed.

16. COMMENT: One commenter asked, "Page 51-Section 4.7(e) 5 – are "all employees" to be offered Hepatitis B vaccinations and is there no longer an option for a practitioner (or employee) to decline the vaccination?" (7)

RESPONSE: The Department thanks the commenter for the comment. Proposed N.J.A.C. 8:27-4.7(e)5 requires the operator of a body art establishment to offer to provide Hepatitis B vaccinations to employees, at the operator's expense and time. Proposed N.J.A.C. 8:27-4.7(d) requires operators to ensure that practitioners and apprentices adhere to applicable provisions of the standard precautions and the bloodborne pathogens standards before, during, and after the performance of body art procedures and whenever a practitioner, apprentice, or another worker has actual or potential occupational exposure. Another worker may be an administrative,

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maintenance, or other employee who does not perform body art procedures, but may still be exposed to bloodborne pathogens during the course of their duties. While operators are required to offer Hepatitis B vaccines, any employee may decline the vaccination. Accordingly, the Department adopts the rule as proposed.

17. COMMENT: Several commenters objected to proposed N.J.A.C. 8:27-4.9(a)1 stating that there are no federal standards for injectable pigments and that adoption of this rule will effectively prohibit the sale and distribution of most pigments to body art establishments in New Jersey. The commenters generally stated that adoption of this requirement would shut down the tattooing industry. (6,8,9,11,12,14)

RESPONSE: The Department agrees in part with the comments and disagrees in part with the comments regarding the interpretation of proposed N.J.A.C. 8:27-4.9(a)1. The Department disagrees that there are no existing United States Department of Health and Human Services, Food and Drug Administration (FDA) standards for certified color additives for injections. These may be found in the Code of Federal Regulations (CFR) at 21 CFR 70.5(b). The FDA has approved color additives for food, drugs, cosmetics, and medical devices. See 21 CFR 73, 74, and 82. Proposed N.J.A.C. 8:27-4.9(a)1 would adopt the federal requirements for color additives applicable to cosmetics in 21 CFR 73, 74, and 82 and apply it to color additives utilized in the manufacture of body art pigments. The proposed rule would also provide for adoption by reference all future regulatory changes promulgated in Title 21 of the CFR. Based on these federal actions, the Department believes that there is a health and safety need to establish purity and safety standards for injectable pigments.

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The Department agrees with the comments, however, that the imposition of federal purity and safety standards applicable to food, cosmetics, and other products may have an adverse effect on the industry in connection with the sale and distribution of pigments which are necessary to the industry. Therefore, the Department intends to consult with federal resources and the regulated industry concerning these matters and will revisit this topic in a future rulemaking. Accordingly, the Department does not adopt proposed N.J.A.C. 8:27-4.9(a)1. Proposed N.J.A.C. 8:27-4.9(a)2 through (a)6 are hereby recodified at N.J.A.C. 8:27-4.9(a)1 through (a)5.

18. COMMENT: Several commenters objected to proposed N.J.A.C. 8:27-4.9(a)2 stating that adoption of this rule will effectively prohibit the sale and distribution of most pigments to body art establishments in New Jersey. (6,8,9,11,12,14)

RESPONSE: The Department disagrees with the comments regarding the interpretation of proposed N.J.A.C. 8:27-4.9(a)2. The requirement that pigments be non-irritating to tissue, stable to light, and inert to tissue metabolism contained in proposed N.J.A.C. 8:27-4.9(a)2 already exist in N.J.A.C. 8:27-7.4(a), which was not amended in this rulemaking. Since N.J.A.C. 8:27-7.4 only applies to tattooing, the Department believes that it is prudent to apply the same standard for pigments used in permanent cosmetics. By proposing this rule in N.J.A.C. 8:27-4.9(a)2, the Department intends that the standards in N.J.A.C. 8:27-7.4(a) should apply to all body art procedures. Existing N.J.A.C. 8:27-8.7(a) already requires that all dyes used for permanent cosmetics shall be nontoxic, nonirritating to tissue, stable to light and inert to tissue metabolism. Proposed N.J.A.C. 8:27-4.9(a)2 would apply this requirement to the balance of

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materials used in permanent cosmetics pigments. The comment does not offer any evidence that the rule will effectively prohibit the sale and distribution of most pigments to body art establishments in New Jersey and the Department is not otherwise aware of any. Accordingly, the Department adopts N.J.A.C. 8:27-4.9(a)2 as proposed.

19. COMMENT: Several commenters objected to proposed N.J.A.C. 8:27-4.9(a)3 on the grounds that there are no federal standards for carcinogens in injectable pigments and that adoption of this rule will effectively prohibit the sale and distribution of most pigments to body art establishments in New Jersey. (6,8,9,11,12,14)

RESPONSE: The Department disagrees with the comments regarding the interpretation of proposed N.J.A.C. 8:27-4.9(a)3. Existing N.J.A.C. 8:27-8.7(b), which was not amended in this rulemaking, already prohibits known carcinogens in pigments used for permanent cosmetics. Proposed N.J.A.C. 8:27-4.9(a)3 would apply this standard to tattoo pigments as well. The Department intends that all pigments, whether used in tattooing or permanent cosmetics, meet a uniform standard. The comment does not offer any evidence that the rule will effectively prohibit the sale and distribution of most pigments to body art establishments in New Jersey and the Department is not otherwise aware of any. Accordingly, the Department adopts N.J.A.C. 8:27-4.9(a)3 as proposed.

20. COMMENT: Several commenters objected to proposed N.J.A.C. 8:27-4.9(a)4 on the grounds that there are no federal standards for substances that have “adverse noncancer health effects” in injectable pigments and that adoption of this rule will effectively prohibit the sale and distribution of most pigments to body art establishments in New Jersey. (6,8,9,11,12,14)

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RESPONSE: The Department disagrees with the comments regarding the interpretation of proposed N.J.A.C. 8:27-4.9(a)4. Existing N.J.A.C. 8:27-7.4(a) and 7.4(b), which were not amended in this rulemaking, already prohibits toxic pigments in tattooing and permanent cosmetics pigments. Proposed N.J.A.C. 8:27-4.9(a)4 would reiterate these requirements for nontoxic pigments under Subchapter 4. The Department will revisit this topic in a future rulemaking and may propose to consolidate these requirements under one rule. All manufacturers of pigments already must comply with this rule and the comment that the rule will effectively prohibit the sale and distribution of most pigments to body art establishments in New Jersey is unsubstantiated. Accordingly, the Department adopts N.J.A.C. 8:27-4.9(a)4 as proposed.

21. COMMENT: A commenter objected to proposed N.J.A.C. 8:27-4.9(c), stating that pigment manufacturers are not required by federal law to provide material safety data sheets (MSDSs) for their products and requiring them to do so with regard to pigments may cause some of them to cease sales and distribution of their products to body art establishments in New Jersey. (6)

RESPONSE: The Department agrees with the comment that there is no federal regulation requiring pigment manufacturers to develop and provide MSDSs. Since many pigment manufacturers are located in other states and countries where MSDSs are not required for pigments, requiring MSDSs for pigments sold or distributed into New Jersey could become burdensome and impractical, and possibly deter manufacturers from selling and distributing pigments into the State. Accordingly, the Department does not adopt proposed N.J.A.C. 8:27-4.9(c).

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22. COMMENT: A commenter requested clarification concerning qualification of body piercing practitioners and apprentices, and specifically whether the requirement for ten prior client application forms proposed in N.J.A.C. 8:27-6.1(a)2 is replacing the existing requirement for three signed testimonials. (6)

RESPONSE: The Department confirms that the proposed N.J.A.C. 8:27-6.1(a)2 replaces the existing requirement for three signed testimonials with ten prior client application forms. The Department believes that providing prior application forms is a more valid documentation of proof of experience than signed testimonials and increasing the number required to ten demonstrates adequate experience to be qualified as a practitioner. The Department does not believe that these requirements are burdensome or impractical to attain. Accordingly, the Department adopts N.J.A.C. 8:27-6.1(a)2 as proposed.

23. COMMENT: One commenter stated that proposed N.J.A.C. 8:27-6.2(a)1, which requires jewelry to not have external threads, is a proper standard for the industry. The commenter further stated that sterilization should be the only acceptable means of cleaning instruments and jewelry used in body piercing. Accordingly, the Department should not adopt proposed N.J.A.C. 8:27-6.2(a)2. (1)

RESPONSE: The Department thanks the commenter for the comment in support of the rule at N.J.A.C. 8:27-6.2. The Department disagrees with the comment that disinfection is not an acceptable means of cleaning instruments and jewelry used in body piercing. The Department is not aware of scientific studies that demonstrate that high level disinfection of body and ear piercing jewelry is inadequate for preventing infections. A

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review of other states' regulations reveals that the majority of states accept either disinfection or sterilization. Requiring sterilization of jewelry would force many body and ear piercing establishments to purchase, maintain, and operate an autoclave and related supplies, which would impose a significant financial cost to them. The cost range for autoclaves are estimated to be between $1,350 and $22,000. The biological and chemical indicators and cleaning supplies required to properly operate and maintain an autoclave adds several hundred dollars to operational costs per year. Accordingly, the Department adopts N.J.A.C. 8:27-6.2 as proposed.

24. COMMENT: One comment stated that there was an error at proposed N.J.A.C. 8:27-7.1(a) which referred to "piercing" instead of "tattooing." The comment stated that a correction should be made so that the rule referred to "tattooing." (15)

RESPONSE: The Department disagrees with the comment. The word "piercing" does not appear at proposed N.J.A.C. 8:27-7.1(a). The proposed rule uses the correct term, "tattooing." Therefore, the Department adopts N.J.A.C. 8:27-7.1(a) as proposed.

25. COMMENT: Two commenters stated that proposed N.J.A.C. 8:27-7.1(b) is unclear because the rule doesn't specify what activities make up the 2000 hours of required apprenticeship time. (6, 7)

RESPONSE: The Department disagrees with the comment. It would be anomalous and unduly burdensome to require an operator to monitor actual tattooing time by an apprentice until it adds up to 2000 hours, which could take years. There is a general maxim in rule interpretation that says a rule should not be read in a manner that achieves an absurd result. The Department considers the 2000 hour requirement to

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include all activities performed while at a tattoo establishment, including tattooing, training, equipment preparation, equipment and facility cleaning, disinfection, sterilization if applicable, record maintenance, and other activities required for operating a body art establishment. Accordingly, the Department adopts N.J.A.C. 8:27-7.1(b) as proposed.

26. COMMENT: One commenter stated, “Proposed new N.J.A.C 8:27-8.1 (page 18-19) establishing minimum standards in the appoint [sic] of practitioners and apprenticeships. This section is not clear to me. Why would there need to be an alternative way to meet the 15 minimum apprenticeship requirements? Regardless of where a practitioner is trained, they should have to meet the NJ State Requirements for 15 apprenticeships (6 cases are included in the permanent makeup training requirements in NJ). If we allow this to be bypassed in any way, we will have practitioners training in other states, especially Philadelphia who does not have this requirement. They will do this to avoid the apprenticeship requirements which cost them additional money and time. When registering for our training, they often complain about the additional cost and time required for apprenticeships. But these apprenticeships are essential to maintain the proper standards for the industry regarding training practitioner and keeping the public safe. This would have a negative economic and job impact for New Jersey Trainers and Instructors. This is also extremely concerning issues [sic] because the suggested “one of each procedure” is not enough to qualify a practitioner to work in New Jersey.” (13)

RESPONSE: The Department disagrees with the comment. Proposed N.J.A.C. 8:27-8.1(a)1 and N.J.A.C. 8:27-8.1(c) would allow an experienced permanent cosmetics

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apprentice or practitioner from another state or country, where the requirement for training by a certified trainer or instructor does not exist, to become approved in New Jersey, without completing a full apprenticeship. Both rules, however, would still require successful completion of a basic training course taught by an instructor or trainer. Proposed N.J.A.C. 8:27-8.1(b) would also require a practitioner to successfully complete a basic training course and obtain a passing grade on one of the approved permanent practitioner examinations. Finally, proposed N.J.A.C. 8:27-8.1(c) would require the prospective practitioner to perform 1 lip lining or shading procedure, 1 eyelining or eyelash enhancement procedure, and 1 eyebrow simulation procedure under the supervision of a certified trainer or instructor. The Department has determined that the aforementioned requirements provide adequate evidence of competency to perform permanent cosmetics procedures. Accordingly, the Department adopts N.J.A.C. 8:27-8.1 as proposed.

27. COMMENT: One commenter stated that the 100 hour PMU training program, documentation of 15 procedures, and 16 hour hands on areola restoration are sufficient to qualify an individual as a practitioner. The commenter stated that the one year waiting period and documentation of 50 permanent makeup procedures is unnecessary and unduly burdensome. The commenter points out that many of the individuals seeking to do this kind of work are women who are breast cancer survivors wanting to give back and perform these procedures for other survivors. The unduly burdensome requirements will discourage applicants. (13)

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RESPONSE: The Department agrees with the comments. The Department has reconsidered proposed N.J.A.C. 8:27-8.1(d)1 and 8.1(d)2 and agrees that these requirements are beyond what is necessary to qualify an applicant. The Department does not adopt proposed N.J.A.C. 8:27-8.1(d)1 and N.J.A.C. 8:27-8.1(d)2. The Department adopts the remainder of the rule as proposed.

28. COMMENT: One commenter stated that the one year experience requirement to learn the skill of camouflaging found at proposed N.J.A.C. 8:27-8.1(e)1 should be shortened to 6 months. The commenter states that 6 months is enough time to develop a good understanding of color theory which is necessary to match skin tone. The commenter also states that the requirement to personally perform 100 PMU cosmetic procedures at proposed N.J.A.C. 8:27-8.1(e)2 is excessive and not necessary to learn the techniques required to perform camouflaging. (13)

RESPONSE: The Department agrees with the comment that a one year experience requirement to learn the skill of camouflage is excessive, and that a lesser experience requirement would still protect clients undergoing camouflage repair because this client population generally has significant underlying medical conditions. Accordingly, the Department reduces the experience requirement at N.J.A.C. 8:27-8.1(e)1 upon adoption from one year to 6 months. The Department agrees with the comment that 100 PMU cosmetic procedures at N.J.A.C. 8:27-8.1(e)2 is excessive and not necessary to learn the techniques required to perform camouflaging. Accordingly, the Department does not adopt N.J.A.C. 8:27-8.1(e)2.

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29. COMMENT: One commenter stated, with respect to the skin preparation procedures proposed at N.J.A.C. 8:27-8.3(a)2, that the Department should not adopt a standard using isopropyl alcohol of at least 70% concentration because isopropyl alcohol of at least 70% concentration can be dangerous or too harsh for the eye area when doing eyeliners. The commenter advocated a rule that would instead prepare the skin with diluted green soap for eyeliner, alcohol wipes for brows and lips, and Hibiclens for areola restoration. (13)

RESPONSE: The Department disagrees with the comment. Green soap is a vegetable, oil and glycerine-based soap containing 30% isopropyl alcohol. Green soap is mildly antiseptic, but it does not have the highly germicidal properties of 70% isopropyl alcohol. The Department considers alcohol wipes containing at least 70% isopropyl alcohol as meeting the proposed requirement, but disagrees with using green soap for eyeliner procedures without the application of a disinfectant afterwards. The commenter also proposed the use of Hibiclens for areola restoration procedures. The Department intends to consider alternative disinfectants with germicidal equivalency to 70% or higher isopropyl alcohol in future rulemaking. Accordingly, the Department adopts N.J.A.C. 8:27-8.3(a)2 as proposed.

30. COMMENT: One comment stated that the enforcement rules at proposed Subchapter 11 are excessive and tirelessly over-worded but the comment does not identify specific provisions in the rule to which the comment may apply. The comment stated that proposed N.J.A.C. 8:27-11.3 is ambiguous and that the standard for determining when a practitioner has demonstrated gross incompetence within the

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meaning of proposed N.J.A.C. 8:27-11.3(b)5 is subjective and needs to be more clearly defined. The comment included a link to Minnesota statutes as an example of more precise and appropriate wording. (6)

RESPONSE: The Department disagrees with the comment. The comment's characterization of proposed Subchapter 11 was not supported with examples by the commenter. Proposed Subchapter 11 is clearly written and establishes common sense rules for inspections, inspection reports, and for operators to submit plans of correction to health authorities to correct deficiencies. Proposed Subchapter 11 provides a non-exclusive list of examples of conditions that constitute an imminent threat to the public health at proposed N.J.A.C. 8:27-11.3(b) in a transparent manner. The Department disagrees that gross incompetence needs to be more clearly defined at proposed N.J.A.C. 8:27-11.3(b)5 in connection with practitioner skills. Gross incompetence would be determined by subject matter experts who are qualified by credentials and experience to render expert opinions concerning what constitutes gross incompetence. The Minnesota statutes found via the link in the comment did not contain any enforcement provisions and were therefore not instructive. Accordingly, the Department adopts N.J.A.C. 8:27-11 as proposed.

31. COMMENT: One comment stated that there needs to be better provisions for enforcement and penalties for a person who performs body art in an unlicensed location. The comment also stated that there needs to be clear enforcement and penalties for a body art establishment that operates without a trainer on the premises where an apprentice is performing body art work. (7)

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RESPONSE: The Department disagrees with the comment. Proposed N.J.A.C. 8:27-11.4 would provide for penalties for any person who violates any provision of these rules, which would include the violation of performing body art in an unlicensed location. Proposed N.J.A.C. 8:27-11.3(c)5 would provide for penalties in the event that an apprentice is found performing body art work without being under the direct supervision of a trainer or instructor. Accordingly, the Department adopts the rule as proposed.

32. COMMENT: One comment stated that a body art establishment should be required to issue a receipt that identifies the establishment, the date of the procedure, the work performed and the artist who performed the body art work. The comment did not provide a reason for the proposed requirement. (7)

RESPONSE: The comment is outside the scope of the proposed rulemaking. Since the comment did not state a reason for the proposed requirement or identify a provision in N.J.A.C. 8:27, the Department is unable to consider it further.

33. COMMENT: Three commenters inquired about the legality of and penalties for performing body art, specifically permanent cosmetics procedures, in establishments licensed and inspected by the Department of Law and Public Safety, Office of the Attorney General, Division of Consumer Affairs, New Jersey Board of Cosmetology and Hairstyling (the Board). (4,7,13)

RESPONSE: The comment is outside the scope of the proposed rulemaking. The proposed rule does not prohibit the performance of cosmetology procedures, provided that they occur in a room separate from body art procedures and do not cause

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contamination of work surfaces, as per existing N.J.A.C. 8:27-3.1(c). However, the Department is aware that the Board prohibits body art procedures in cosmetology and hairstyling establishments as per N.J.A.C. 13:28-2.15, and therefore the operator of establishments offering both services must satisfy the Board's rules, as well as N.J.A.C. 8:27. The commenters' request for consideration of a penalty for body art procedures being performed in the same establishment as work that is licensed and overseen by the New Jersey Board of Cosmetology and Hairstyling is already provided for in N.J.A.C. 13:28-4.1 et seq.

34. COMMENT: Two commenters stated that the Department should establish a licensing scheme for body art practitioners and operators that would encompass licensing, recordkeeping, and continuing education, similar to physicians or cosmetologists. (7,13)

RESPONSE: The comments are outside the scope of the proposed rulemaking. Regardless, the Department disagrees that it should establish a licensing scheme as described in the comments because the current system of experiential, training, and credentialing requirements adequately addresses the needs of the industry without the added labor intensive measures and expenses that a licensing scheme would require.

35. COMMENT: One comment stated that local health authorities improperly take enforcement actions, such as orders to discard, against pigments that have exceeded the expiration date established by their manufacturer. The comment stated that although there is nothing in existing N.J.A.C. 8:27 that requires local health authorities

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to do this, the commenter does not want expiration date enforcement to be made a part of the rule in the future because pigments get better with age. (5)

RESPONSE: The comment is outside the scope of the proposed rulemaking because this rule proposal does not address manufacturer's expiration dates. Regardless, the Department disagrees with the comment regarding expiration dates on containers of pigments. The Code of Federal Regulations requires an expiration date on color additives if stability data require it pursuant to 21 C.F.R. 70.25(a)(4). Accordingly, the manufacturer determines if an expiration date is required on color additives utilized in making pigments based upon stability data. It wouldn't make sense to use an unstable pigment in body art. Accordingly, health authorities correctly take enforcement actions concerning pigments that have exceeded the manufacturer's expiration date.

36. COMMENT: One comment states that the terms "tattoo apprentice" and "tattoo apprenticeship" are not recognized by the Department of Labor. The comment requests the Department of Health to make revisions to N.J.A.C. 8:27 to ensure that tattoo apprentices are "recognized by the NJ Department of Labor, so that tattoo practitioners can continue to train new artists without being left vulnerable to a wage claim at the Department of Labor." (3)

RESPONSE: The comment is outside the scope of the proposed rulemaking because it refers to a hearing that was held at the Department of Labor. Accordingly, the grievance presented by the commenter cannot be addressed by the Department of Health in this rulemaking.

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37. COMMENT: One commenter stated that the rule proposal should have addressed training requirements for microblading procedures and salt lifting or lightening. (13)

RESPONSE: The comment is outside the scope of the proposed rulemaking. The Department intends to explore training requirements for these subjects with a stakeholder group for possible inclusion in a future rulemaking.

Summary of Agency Initiated Changes:

As proposed, N.J.A.C. 8:27-11.2(a) would have required the local health authority to conduct an inspection of a body art establishment every time that establishment submitted an adverse reaction notification pursuant to N.J.A.C. 8:27-4.6. Upon reconsideration, the Department has concluded that a mandatory inspection by the local health authority following notification of an adverse reaction to a body art procedure unnecessarily removes discretion from the local health authority to not perform an inspection where one may not be warranted. In addition, mandatory inspections following notification of an adverse reaction may discourage body art establishments from reporting adverse reactions, depriving local health authorities of information that could reveal trends or patterns in connection with adverse reactions that would be valuable in identifying adulterated batches of pigments or supplies, for example. Therefore, the Department adopts N.J.A.C. 8:27-11.2(a) without the language triggering a mandatory inspection by the local health authority following notification of an adverse reaction to a body art procedure.

Federal Standards Statement

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The rules proposed for readoption with amendments, repeals, and new rules are not proposed under the authority of, or to implement, comply with, or participate in, any program established under Federal law or under a State statute that incorporates or refers to Federal law, standards, or requirements. Therefore, no Federal standards analysis is required.

Full text of the adoption follows. Additions to proposal indicated in bold with asterisks ***thus***; Deletions from proposal indicated with brackets and asterisks *[thus]*:

8:27-2.6 Prohibitions

(a) Operators shall ensure that the following prohibited activities do not occur at a body art or ear-piercing establishment:

1. – 5. (No change from proposal)

[6. The performance of the disciplines of areola restoration, camouflage, or microblading, other than at a permanent cosmetics establishment in accordance with N.J.A.C. 8:27-8.1.]

[7] ***6***. The operation of a body art or ear-piercing establishment other than in accordance with the applicable requirements of this chapter; and

[8] ***7***. The performance of body art or ear piercing in an establishment, unless the operator or a responsible person is present on the premises and supervising the establishment, provided:

i. (No change from proposal)

(b) – (c) (No change from proposal)

…

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8:27-4.9 Pigments

(a) Operators shall ensure that pigments that practitioners and apprentices use to perform body art:

*[1. Comply with applicable Federal standards, such as the Federal Food, Drug, and Cosmetic Act, Title 21 of the United States Code, and regulations promulgated pursuant thereto at Title 21 of the Code of Federal Regulations, including standards for color additives;

2]* ***1***. Are non-irritating to tissue, stable to light, and inert to tissue metabolism;

[3] ***2***. Do not contain substances that are known to be human carcinogens or may reasonably be anticipated to be human carcinogens, as specified in National Toxicology Program, Report on Carcinogens, 14th Edition (2016), Research Triangle Park, NC, United States Department of Health and Human Services, Public Health Service, incorporated herein by reference, as amended and supplemented, and available at http://ntp.niehs.nih.gov/go/roc14;

[4] ***3***. Do not contain substances at exposure levels that are known, or may reasonably be anticipated, to have adverse noncancer health effects as determined by the National Toxicology Program, which are listed at http://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/index.html, incorporated herein by reference, as amended and supplemented;

[5] ***4***. Are stored out of direct sunlight; and

[6] ***5***. Are not subjected to autoclave processing.

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(b) (No change from proposal.)

*[(c) Operators shall:

1. Obtain from pigment suppliers, the safety data sheet for each pigment in use at the establishment; and

2. Maintain and make the safety data sheets, for pigments, topical anesthetics, and disinfectants, available to employees in accordance with applicable Federal and State occupational health and safety laws, and, upon request, to practitioners, apprentices, clients, and health authorities.]*

8:27-8.1 Qualifications of permanent cosmetics practitioners and apprentices

(a) – (c) (No change from proposal.)

(d) An operator shall ensure that a qualified permanent cosmetics practitioner who is to perform the discipline of areola restoration, has the credentials specified at (a) above and:

*[1. Has completed one full year of experience as a full-time permanent cosmetics practitioner, evidence of which is timesheets, paystubs, an employer or operator certification under the penalty of perjury, or other documentation that enables the health authority to confirm the length of the practitioner's practice experience;

2. Has personally performed 50 permanent cosmetics procedures, which can include those at (a)2 and/or (c) above, evidence of which is a copy of the client application for each procedure and a photograph of the completed permanent cosmetics procedure that corresponds to each client application; and

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3]* ***1***. Has successfully completed a training program in areola restoration of at least 16 hours in length provided by a trainer or an instructor, evidence of which is an original certificate, diploma, or other documentation that a training program issues to indicate successful completion.

(e) An operator shall ensure that a qualified permanent cosmetics practitioner who is to perform the discipline of camouflage has the credentials specified at (a) above and:

1. Has completed *[one full year]* ***six months*** of experience as a full-time permanent cosmetics practitioner, evidence of which is timesheets, paystubs, an employer or operator certification under the penalty of perjury, or other documentation that enables the health authority to confirm the length of the practitioner's practice experience;

*[2. Has personally performed 100 permanent cosmetics procedures, which can include those required pursuant to (a)2 and/or (d)2 above, evidence of which is a copy of the client application for each procedure and a photograph of the completed permanent cosmetics procedure that corresponds to each client application; and

3]* ***2***. Has successfully completed a training program in camouflage of at least 16 hours in length provided by a trainer or an instructor, evidence of which is an original certificate, diploma, or other documentation of successful completion that a training program issues.

(f) – (g) (No change from proposal.)

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…

8:27-11.2 Inspection, inspection report, and plan of correction

(a) The local health authority with jurisdiction shall inspect every body art and ear-piercing establishment at least annually *[and upon receipt of an adverse reaction notification pursuant to N.J.A.C. 8:27-4.6]*.

(b) – (l) (No change from proposal.)

…

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